



Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221
July 8, 2003

ENTERED



Dr. Amrit S. Boparai
Analytical Chemistry Laboratory
Argonne National Laboratory-East
9700 South Cass Avenue
Argonne, IL 60439-4837

RE: Issuance of Argonne National Laboratory-East (ANL-E) CARs 03-065 through 03-068 for Audit A-03-18

Dear Dr. Boparai:

The Carlsbad Field Office (CBFO) performed Audit A-03-18 of Argonne national Laboratory-East, on June 24 and 25, 2003. The scope of this audit was the adequacy, implementation, and effectiveness of the quality assurance elements and technical elements related to the procedures and processes used by ANL-E in it's role as the sample preparation contractor for the Headspace Gas Performance Demonstration Program. As a result of this audit, the subject CARs have been issued.

Please determine and document on the enclosed CAR continuation sheets your proposed corrective action plans for the CARs. Please forward the proposed corrective action plans and schedules for completion to me prior to the response due dates identified in CAR block 14.

If you have any questions or comments, please contact me at (505) 234-7442.

M. Lea Chism

M. Lea Chism
Quality Assurance Specialist

Enclosure

cc: w/enclosure
A. Holland, CBFO *ED
K. Watson, CBFO *ED
M. Brown, CBFO *ED
K. Joshi, DOE-CH *ED
A Gabel, DOE-CH *ED
M. Eagle, EPA *ED
S. Zappe, NMED *ED
B. Walker, EEG *ED
A. Arceo, CTAC *ED
C. Watkins, CTAC *ED
D. Gill, CTAC *ED
T. Bowden, CTAC *ED
K. Dunbar, WTS
CBFO QA File
CBFO M&RC

*ED denotes electronic distribution
CBFO:QA:MLC:GS:03-1573:UFC 2300.00

030707



CORRECTIVE ACTION REPORT

1. CAR No.: 03-065	2. Activity Report No.: A-03-18	3. Page <u>1</u> of																
4. Controlling Document: SW-846, Method 8260B Volatile Organic Compounds By Gas Chromatography/Mass Spectrometry (GC/MS), Rev. 2		5. CBFO Assessment Team Leader: Lea Chism																
6. Responsible Organization: ; ANL-E CMT ACL		7. CAQ Was Discussed With: A. Boparai, M. Kalensky																
8. Requirement that was violated: SW-846, Method 8260B, Rev. 2, Section 5.12.1, states, in part: "Initial calibration standards should be prepared at a minimum of five different concentrations from the secondary dilution of stock standards (see Sections 5.7 and 5.8) or from a premixed certified solution."																		
9. Condition Adverse to Quality: The standards used for preparation of calibration standards are used beyond their manufacturer's expiration date. For example, ALM030407 and ALM023835 expired in 2001 but were used to make calibration standards on 2/18/03.																		
10. Suggested Actions (Optional):																		
<table style="width: 100%;"> <tr> <td>11a. Significant CAQ</td> <td>(Yes or No):X</td> </tr> <tr> <td>11b. Work Suspension Recommended</td> <td>(Yes or No):X</td> </tr> <tr> <td>11c. RCRA-Related</td> <td>(Yes or No):X</td> </tr> <tr> <td>11d. Accelerated Corrective Action Required</td> <td>(Yes or No):X</td> </tr> </table>			11a. Significant CAQ	(Yes or No):X	11b. Work Suspension Recommended	(Yes or No):X	11c. RCRA-Related	(Yes or No):X	11d. Accelerated Corrective Action Required	(Yes or No):X								
11a. Significant CAQ	(Yes or No):X																	
11b. Work Suspension Recommended	(Yes or No):X																	
11c. RCRA-Related	(Yes or No):X																	
11d. Accelerated Corrective Action Required	(Yes or No):X																	
12. Types of Actions: Remedial: <u>X</u> Investigative: <u>X</u> Root Cause: <u>X</u> Actions to Preclude Recurrence: <u>X</u>																		
13. CAR Initiator: <u>Dorothy Gill</u> Date: <u>7/02/03</u>																		
<table style="width: 100%;"> <tr> <td colspan="2">14. Response Due Date: <u>08-08-03</u></td> <td>Corrective Action Plan Required: <u>YES</u> NO</td> </tr> <tr> <td colspan="3">Required Corrective Action Completion Date: <u>N/A</u></td> </tr> </table>			14. Response Due Date: <u>08-08-03</u>		Corrective Action Plan Required: <u>YES</u> NO	Required Corrective Action Completion Date: <u>N/A</u>												
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Required Corrective Action Completion Date: <u>N/A</u>																		
<table style="width: 100%;"> <tr> <td style="width: 40%;">15. a. Concurrence: <u>M. Lea Chism</u></td> <td style="width: 20%;">Date: <u>07/08/03</u></td> <td style="width: 20%;">b. <u>N/A</u></td> <td style="width: 20%;">Date:</td> </tr> <tr> <td>Assessment Team Leader</td> <td></td> <td>Responsible Assistant Manager</td> <td></td> </tr> <tr> <td colspan="2">c. <u>N/A</u></td> <td colspan="2">Date:</td> </tr> <tr> <td colspan="2">Quality Assurance Manager</td> <td colspan="2"></td> </tr> </table>			15. a. Concurrence: <u>M. Lea Chism</u>	Date: <u>07/08/03</u>	b. <u>N/A</u>	Date:	Assessment Team Leader		Responsible Assistant Manager		c. <u>N/A</u>		Date:		Quality Assurance Manager			
15. a. Concurrence: <u>M. Lea Chism</u>	Date: <u>07/08/03</u>	b. <u>N/A</u>	Date:															
Assessment Team Leader		Responsible Assistant Manager																
c. <u>N/A</u>		Date:																
Quality Assurance Manager																		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet																		
17. Acceptance of Proposed Corrective Actions:																		
<table style="width: 100%;"> <tr> <td style="width: 60%;">Assessment Team Leader</td> <td style="width: 40%;">Date</td> </tr> </table>			Assessment Team Leader	Date														
Assessment Team Leader	Date																	
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)																		
19a. Verified By: _____																		
Name	Date																	
19b. Trend Cause Code: _____																		
20. Closure: _____																		
Quality Assurance Manager	Date																	

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.:

2. Activity No.:

3. Page ____ of ____

Block #

CORRECTIVE ACTION REPORT

1. CAR No.: 03-066		2. Activity Report No.: A-03-18		3. Page <u>1</u> of <u>2</u>	
4. Controlling Document: SW-846, Method 8260B Volatile Organic Compounds By Gas Chromatography/Mass Spectrometry (GC/MS), Rev. 2 and Method 8000B Determinative Chromatographic Separations, WAP, and QAPD			5. CBFO Assessment Team Leader: Lea Chism		
6. Responsible Organization: : ANL-E CMT ACL			7. CAQ Was Discussed With: A. Boparai, M. Kalensky		
8. Requirement that was violated: (See Continuation Sheet)					
9. Condition Adverse to Quality: (See Continuation Sheet)					
10. Suggested Actions (Optional):					
11a. Significant CAQ (Yes or No):X 11b. Work Suspension Recommended (Yes or No):X 11c. RCRA-Related. (Yes or No):X 11d. Accelerated Corrective Action Required (Yes or No):X					
12. Types of Actions: Remedial: <u>X</u> Investigative: <u> </u> Root Cause: <u> </u> Actions to Preclude Recurrence: <u> </u>					
13. CAR Initiator: <u>Dorothy Gill</u> Date: <u>7/02/03</u>					
14. Response Due Date: <u>08/08/03</u> Corrective Action Plan Required: <u>(YES)</u> NO Required Corrective Action Completion Date: <u>N/A</u>					
15. a. Concurrence: <u>M. Lea Chism</u> <u>07/08/03</u> b. <u>N/A</u> Assessment Team Leader Date Responsible Assistant Manager Date c. <u>N/A</u> Quality Assurance Manager Date					
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet					
17. Acceptance of Proposed Corrective Actions: Assessment Team Leader Date					
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)					
19a. Verified By: <u> </u> <u> </u> Name Date 19b. Trend Cause Code: <u> </u>					
20. Closure: <u> </u> <u> </u> Quality Assurance Manager Date					

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.:03-066

2. Activity No.: A-03-18

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Block # 8 Requirement that was violated:

A. SW-846, Method 8260B, *Volatile Organic Compounds By Gas Chromatography/Mass Spectrometry (GC/MS)*, Rev. 2, Section 7.6.1, states, "The qualitative identification of each compound determined by this method is based on retention time, and on comparison of the sample mass spectrum, after background correction, with characteristic ions in a reference mass spectrum. The reference mass spectrum must be generated by the laboratory using the conditions of this method. The characteristic ions from the reference mass spectrum are defined to be the three ions of greatest relative intensity, or any ions over 30% relative intensity if less than three such ions occur in the reference spectrum." Method 8000B, *Determinative Chromatographic Separations* Section 7.6.1, states, "Before establishing retention time windows, make sure that the chromatographic system is operating reliably and that the system conditions have been optimized for the target analytes and surrogates in the sample matrix to be analyzed."

B. WAP, Table B 3-3 *Summary of Laboratory Quality Control Samples and Frequencies for Gas Volatile Organic Compound Analysis*; Method Performance Samples must meet method QAOs (WAP Table B3-2 provides methods QAOs for accuracy and precision).

C. QAPD, Rev. 5, Section 2.1.2.8, states "Methods for demonstrating that the work was performed as required (such as provisions for recording inspection and test results, check-off lists, or sign-off blocks), and Section 2.1.2.9. Identification and classification of QA records to be generated by the implementing procedure

D. WAP, Table B1-1, *Gas Sample Requirements*, Holding Temperatures 0-40°C

Block # 9 Condition Adverse to Quality:

Adequacy issue: Procedure ACL-168, Rev. 5, does not address the following:

- A. The initial calibration section (8.4.1) does not describe how retention time and retention time windows are determined.
- B. The procedure does not require generation of method precision and accuracy data.
- C. The procedure does not describe what records are generated by this procedure, nor how these records are dispositioned.
- D. The procedure does not address the holding temperature requirement for VOCs SUMMA canister, hence there was no documentation for monitoring the temperature in the area for storage of PDP and calibration canisters.

CBFO CORRECTIVE ACTION REPORT

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1. CAR No.:	2. Activity No.:	3. Page ____ of ____
<p>Block #_</p>		

CORRECTIVE ACTION REPORT

1. CAR No.: 03-067	2. Activity Report No.: A-03-18	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: SOP ACL-211, Revision 4	5. CBFO Assessment Team Leader: Lea Chism	
6. Responsible Organization: ANL-E CMT ACL	7. CAQ Was Discussed With: Mike Kalensky	
<p>8. Requirement that was violated:</p> <p>A) SOP ACL-211, Section 4.6.1 states, "In an ACL-approved serialized notebook, maintain a log of the location and shipment and content of all canisters used in the HSGPDP."</p> <p>B) SOP ACL-211, Section 3, Receipt Inspection states, "Upon receipt of the HSGPDP gas cylinders from the vendor, the ACL shall verify that the compounds listed on the certificate of analysis attached to each cylinder are the same as ordered and that their concentrations are approximately the same as ordered. The verification shall be documented by signing (or initialing) and dating the certificate of analysis with a statement: "Received by ANL."</p>		
<p>9. Condition Adverse to Quality:</p> <p>A) There is no record of all canisters used in the HSG PDP, since only those canisters shipped in a given cycle is recorded in a serialized notebook. The canisters not being used in the most recent cycle are not accounted for in ACL documentation.</p> <p>B) There is no documentation of receipt inspection to verify that the compounds listed on the certificate of analysis attached to each cylinder are the same as ordered and that their concentrations are approximately the same as ordered. The words "received by ANL" are not present on any of the certificates of analysis associated with the calibration standards or PDP samples.</p>		
10. Suggested Actions (Optional):		
<p>11a. Significant CAQ (Yes or No): No</p> <p>11b. Work Suspension Recommended (Yes or No): No</p> <p>11c. RCRA-Related (Yes or No): No</p> <p>11d. Accelerated Corrective Action Required (Yes or No): No</p>		
12. Types of Actions: Remedial: <u>X</u> Investigative: _____ Root Cause: _____ Actions to Preclude Recurrence: _____		
<p>13. CAR Initiator: <u>Cliff Watkins</u> Date: <u>7/02/03</u></p>		
<p>14. Response Due Date: <u>08/08/03</u> Corrective Action Plan Required: <u>(YES)</u> NO</p> <p>Required Corrective Action Completion Date: <u>N/A</u></p>		
<p>15. a. Concurrence: <u>M. Lea Chism</u> <u>07/08/03</u> b. <u>N/A</u></p> <p style="text-align: center;">Assessment Team Leader Date Responsible Assistant Manager Date</p> <p style="text-align: center;">c. <u>N/A</u></p> <p style="text-align: center;">Quality Assurance Manager Date</p>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
<p style="text-align: center;">_____ Assessment Team Leader Date</p>		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
<p>19a. Verified By: _____ Date: _____</p> <p style="text-align: center;">Name Date</p>		
19b. Trend Cause Code: _____		
<p>20. Closure: _____</p> <p style="text-align: center;">Quality Assurance Manager Date</p>		

CBFO CORRECTIVE ACTION REPORT

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1. CAR No.:

2. Activity No.:

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CORRECTIVE ACTION REPORT

1. CAR No.: 03-068	2. Activity Report No.: A-03-18	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: SOP ACL-158, Rev. 4	5. CBFO Assessment Team Leader: Lea Chism	
6. Responsible Organization: ANL-E CMT ACL	7. CAQ Was Discussed With: Mike Kalensky	
<p>8. Requirement that was violated: SOP ACL-158, Rev. 4, Section 3, states, in part, "<i>Apparatus and Materials</i> -Bourdon type pressure gauge: 0 to 345 kPa (0 to 50 psig) to monitor zero air pressure. -Humidifier: 300 mL stainless steel cylinder containing high performance liquid chromatography (HPLC) grade deionized water to provide moisture to the zero air supply. Dry zero air impinges on the surface of the water and sweeps the headspace of the reservoir."</p>		
<p>9. Condition Adverse to Quality: The Bourdon style pressure gauge used to monitor zero air pressure reading between 0 and 345 kPa and HPLC grade water are not being used on the canister cleaning manifold. They used a pressure gauge that measures in mm Hg and water that is purified using the NANO pure system.</p>		
10. Suggested Actions (Optional):		
<p>11a. Significant CAQ (Yes or No): No 11b. Work Suspension Recommended (Yes or No): No 11c. RCRA-Related (Yes or No): No 11d. Accelerated Corrective Action Required (Yes or No): No</p>		
12. Types of Actions: Remedial: <u>X</u> Investigative: _____ Root Cause: _____ Actions to Preclude Recurrence: _____		
13. CAR Initiator: <u>Cliff Watkins</u> Date: <u>7/02/03</u>		
14. Response Due Date: <u>08/08/03</u> Corrective Action Plan Required: <u>YES</u> NO Required Corrective Action Completion Date: <u>N/A</u>		
<p>15. a. Concurrence: <u>M. Lea Chism</u> <u>07/08/03</u> b. <u>N/A</u> Assessment Team Leader Date Responsible Assistant Manager Date c. <u>N/A</u> Quality Assurance Manager Date</p>		
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CBFO CORRECTIVE ACTION REPORT

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3. Page ___ of ___

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